

REMARKS

In the Office Action, the Specification including the Abstract is objected; claims 1-4 are rejected under 35 U.S.C. § 101; claims 1-4 and 15 are rejected under 35 U.S.C. § 112, first paragraph; claims 1-23 are rejected under 35 U.S.C. § 112, second paragraph; claims 1-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting; and claims 1-23 are rejected under 35 U.S.C. § 102 or § 103. Claims 1, 3, 4, 6, 7, 9, 10, 12-20, 22, and 23 have been amended. Applicants believe that the rejections have been overcome or are improper in view of the amendments and for the reasons set forth below.

At the outset, the Specification including the Abstract has been objected as previously discussed. In response, Applicants have amended the Specification including the Abstract and as such believe that the objections have been addressed. Therefore, Applicants respectfully request that the objections to the Specification including the Abstract be withdrawn.

In the Office Action, claims 1-4 are rejected under 35 U.S.C. § 101. In response, Applicants have amended independent claim 1 to recite a biologically pure culture of lactic acid bacterium strain. Therefore, Applicants believe that the requirements pursuant to 35 U.S.C. § 101 have been satisfied.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 1-4 and 15 are rejected under 35 U.S.C. § 112, first paragraph. The Patent Office asserts that the microorganism recited in the claims must be obtainable by a repeatable method set forth in the Specification or otherwise be readily available to the public. However, this requirement may be satisfied by a deposit of a microorganism. In this regard, Applicants respectfully submit that a deposit of the microorganism, namely, *Lactobacillus paracasei* CNCM I-2116 has been made pursuant to PCT Rule 13 *bis* during the examination of the related International Application No. PCT/EP00/01797. A copy of a document relating to the deposit as discussed above is attached herewith as Exhibit A. Therefore, Applicants believe that the requirements pursuant to the first paragraph of 35 U.S.C. § 112 have been satisfied.

Accordingly, Applicants believe that the rejection of claims 1-4 and 15 under 35 U.S.C. § 112, first paragraph be withdrawn.

In the Office Action, claims 1-23 are rejected under 35 U.S.C. § 112, second paragraph. In response, claims 1-4, 6, 7, 9, 10, 12-20, 22, and 23 have been amended to address most of the issues raised with respect to this rejection. In this regard, Applicants believe that these changes were made for clarification purposes and thus assert that the changes should not be deemed as an intention on the part of Applicants to narrow or disclaim any claimed subject matter in view of same. Regarding any remaining alleged issues, Applicants believe these to be improper. In this regard, Applicants believe that the claimed subject matter at issue is fully supported in the Specification in such a way that one skilled in the art would understand the scope and content of same.

Based on at least these reasons, Applicants believe that the requirements pursuant to 35 U.S.C. § 112, second paragraph, have been satisfied. Therefore, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 1-23 have been rejected under 35 U.S.C. § 102 or § 103 in view of EP 0861905. Applicants believe that this rejection should be withdrawn as set forth below.

Of the pending claims at issue, claims 1, 6, 9, 10, 18, and 20 are the sole independent claims. Independent claim 1 recites a biologically pure culture of lactic acid bacterium belonging to a genus *Lactobacillus* capable of adhering to and colonizing an intestinal mucosa and capable of preventing infection of intestinal epithelial cells by rotaviruses wherein the lactic acid bacterium strain is capable of growing in presence of up to about 0.4% bile cells. Independent claim 6 recites a method for preparing an ingestible support material that uses the lactic acid bacterium strain. Independent claim 9 recites a method for the treatment of a disorder that administers to a patient suffering the disorder the lactic acid bacterium strain. Independent claim 10 recites a pharmaceutical composition that includes the lactic acid bacterium strain. Independent claim 18 recites a method for preventing a disorder that includes administering the lactic acid bacterium strain. Independent claim 20 recites a food that includes the lactic acid bacterium strain.

The microorganisms of the present invention have been shown to exhibit a number of desirable properties. They are gram positive, catalase negative, NH_3 from arginine negative and carbon dioxide production negative. The microorganisms can produce L(+) lactic acid and are

capable of growth in the presence of bile salts in a concentration of up to about 0.4% and may effectively prevent infection of epithelial cells by rotaviruses. See, Specification, p. 3, lines 21 to page 4, line 2.

In contrast, Applicants believe that the cited art is deficient with respect to the claimed invention.

The cited reference fails to provide any suggestion against which agents the lactobacilli are providing any activity. In this regard, the cited reference merely discloses that strains are opposing pathogens purportedly through a lowering of the pH of the intestinal environment. See, EP0861905, page 4, lines 33-35. Indeed, the term "pathogens" is not specifically defined and may therefore relate to parasites, fungi, bacteria, viruses or even to inorganic particles. Moreover, nowhere does the cited art disclose or suggest viruses including rotaviruses as claimed. The primary focus of the cited art relates to lactic acid bacteria that are purportedly designed to reconstitute the microflora that has been lost during, for example, an antibiotic treatment or after anti-tumor radiotherapy. Thus, the cited reference fails to disclose or suggest how to protect intestinal epithelial cells against infection by rotaviruses.

Further, rotaviruses exhibit a relatively high stability and would not be affected by a relatively slow lowering of the pH of the extracellular intestinal environment caused by organic acids as disclosed in the cited reference. The cited reference also fails to disclose or suggest lactobacillus strains that are capable of growth in the presence of up to 0.4% bile salts as claimed. Therefore, Applicants believe that one skilled in the art would conclude that the strains as disclosed in the cited reference do not exhibit any protective property against an infection of the human intestine by rotaviruses as required by the claimed invention.

Based on at least these reasons, Applicants believe that the cited reference is deficient with respect to the claimed invention. Therefore, Applicants believe that the cited reference fails to disclose or suggest the claimed invention.

Accordingly, Applicants respectfully request that the anticipation and obviousness rejections in view of EP0861905 be withdrawn.

In the Office Action, claims 1-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting. More specifically, claims 1-23 are provisionally rejected as allegedly being unpatentable over claims 1-22 of copending application No.

09/936,489 and copending application No. 09/936,452. As the obviousness-type double patenting rejections are provisional, Applicants assert that they plan to submit a terminal disclaimer, if necessary, to overcome the provisional rejections once either one or both of the copending applications have issued. Therefore, Applicants believe that they have been responsive to the provisional rejections at this stage in the prosecution.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration for the same.

Respectfully submitted,

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Dated: December 30, 2003

Applicant's or agent's
file reference

80135/WO

International application No.

PCT/EP00/01797

INDICATIONS RELATING TO DEPOSITED MICROORGANISM
OR OTHER BIOLOGICAL MATERIAL

(PCT Rule 13bis)

A. The indications made below relate to the deposited microorganism or other biological material referred to in the description
on pages 3, 5, 7, 18, line s 25, 12, 12, 16

B. IDENTIFICATION OF DEPOSIT

Further deposits are identified on an additional sheet ☐

Name of depositary institution

CNCM
COLLECTION NATIONALE DE CULTURES DE MICROORGANISMES

Address of depositary institution (including postal code and country)

Institut Pasteur
28, Rue du Docteur Roux,
F-75724 Paris Cedex 15

Date of deposit

12.01.1999

Accession Number

I-2116

C. ADDITIONAL INDICATIONS (leave blank if not applicable)

This information is continued on an additional sheet ☐

D. DESIGNATED STATES FOR WHICH INDICATIONS ARE MADE (if the indications are not for all designated States)

E. SEPARATE FURNISHING OF INDICATIONS (leave blank if not applicable)

The indications listed below will be submitted to the International Bureau later (specify the general nature of the indications e.g., "Accession Number of Deposit")

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Authorized officer

TRAITE DE BUDAPEST ~~OR LA RECONNAISSANCE~~
INTERNATIONALE DU DEPOT DES MICRO-ORGANISMES
AUX FINS DE LA PROCEDURE EN MATIERE DE BREVETS

FORMULE INTERNATIONALE

DESTINATAIRE :

RECEPISSE EN CAS DE DEPOT INITIAL,
délivré en vertu de la règle 7.1 par
l'AUTORITE DE DEPOT INTERNATIONALE
identifiée au bas de cette page

SOCIETE DES PRODUITS NESTLE S.A.
Patents department
Avenue Nestlé 55
CH-1800 Vevey

NOM ET ADRESSE
DU DEPOSANT

I. IDENTIFICATION DU MICRO-ORGANISME	
Référence d'identification donnée par le DEPOSANT : NCC 2461	Numéro d'ordre attribué par l'AUTORITE DE DEPOT INTERNATIONALE : I - 2116
II. DESCRIPTION SCIENTIFIQUE ET/OU DESIGNATION TAXONOMIQUE PROPOSEE	
<p>Le micro-organisme identifié sous chiffre I était accompagné :</p> <p><input checked="" type="checkbox"/> d'une description scientifique</p> <p><input checked="" type="checkbox"/> d'une désignation taxonomique proposée</p> <p>(Cocher ce qui convient)</p>	
III. RECEPTION ET ACCEPTATION	
<p>La présente autorité de dépôt internationale accepte le micro-organisme identifié sous chiffre I, qu'elle a reçu le 12 JANVIER 1999 (date du dépôt initial)¹</p>	
IV. RECEPTION D'UNE REQUETE EN CONVERSION	
<p>La présente autorité de dépôt internationale a reçu le micro-organisme identifié sous chiffre I le (date du dépôt initial) et a reçu une requête en conversion du dépôt initial en dépôt conforme au Traité de Budapest le (date de réception de la requête en conversion)</p>	
V. AUTORITE DE DEPOT INTERNATIONALE	
<p>Nom : CNCM Collection Nationale de Cultures de Microorganismes</p> <p>Adresse : INSTITUT PASTEUR 28, Rue du Docteur Roux F-75724 PARIS CEDEX 15</p>	<p>Signature(s) de la (des) personne(s) compétente(s) pour représenter l'autorité de dépôt internationale ou de l'(des) employé(s) autorisé(s) : Mme Y. CERISIER Directeur Administratif de la CNCM</p> <p><i>Y. Cerisier</i></p> <p>Date : Paris, le 12 février 1999</p>

¹ En cas d'application de la règle 6.4.d), cette date est la date à laquelle le statut
d'autorité de dépôt internationale a été acquis.